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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/477,977	01/05/2000	JOHN H. BURTON	825.001US2	1025

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EXAMINER
KEARNEY, ROSILAND STACIE

ART UNIT	PAPER NUMBER
3739	10

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/477,977	Applicant(s) BURTON ET AL.	
	Examiner Rosiland S Kearney	Art Unit 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 May 2000* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-24,26-37,39 and 40* is/are rejected.

7)☒ Claim(s) *25 and 38* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 3, 5, 6, & 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Hickey et al. Hickey et al. disclose an implantable device comprising an expandable element (19) attached to an elongated conduit element which includes a rear port portion (see Figure 2) connected to a first passageway (20). The device also includes a second passageway as illustrated in Figure 3, a guide probe member as recited in column 3 lines 14-17 and a source containing a flowable material as suggested in column 2 lines 56-57.

3. Claims 13-17, 19-24, 27-32, 34-37, 39 and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by Haber. Haber discloses a method for variable restricting a body lumen. Figures 5-9 illustrate the steps of guiding an elongate implantable device (1) into the body tissue, the elongate implantable device having an expandable element (2) and a port portion, injecting a flowable material into the implantable device (col. 5 lines 38-51 & Figure 9) and guiding the device over an elongate probe member (4). **In regards to claims 15 & 16** see column 5 lines 38-41. **Regarding claims 22 and 37** Haber discloses the use of a radio opaque isotonic solution to fill the expandable member (column 5 lines 40-45). During fluoroscopy a radio opaque solution is used to locate the device that is to be visualized. Therefore, it is inherent in Habers'

disclosure of the use of a radio opaque solution during implantation of the device that fluoroscopy is utilized.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 2 & 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hickey et al. as applied to claim 1 above, and further in view of Whitehouse et al. Hickey et al. teach all of the limitations of the claims except a septum being contained in the cavity of the first passageway by a clamp. Whitehouse et al. disclose that is well known in the art to use a septum to provide a self-sealing seal between a needle and catheter. It would have been obvious to one of ordinary skill in the art at the time the invention was made to clamp a septum in the cavity of the catheter to provide a self-sealing seal between the needle and the catheter so that the inflation medium does not leak out once the needle is removed.

6. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hickey et al. as applied to claim 1 above, and further in view of McIntyre et al. Hickey et al. explicitly teach all of the limitations of the claim except the expandable element being attached to the conduit by an adhesive material. McIntyre et al. teach that it is old and well known in the art to

attach an expandable element to a conduit via bonding with liquid-tight seals such as adhesives. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to attach the expandable element of Hickey et al. to the conduit with and adhesive as taught by McIntyre et al. as a mere design choice based on the preference of the user.

7. Claims 9 & 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hickey et al. Hickey et al. explicitly teach all of the limitations of the claims except the probe member being pointed at the forward end or being a flexible guidewire. Stylets and guidewires are extremely old and well known probe members in the art therefore to select one as the probe member of Hickey et al. would have merely involved routine skill in the art.

8. Claims 11 & 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hickey et al. as applied to claim 8 above, and further in view of Whitehouse et al. and Salama. Hickey et al. teach all of the limitations of the claims except a septum being contained in the cavity of the first passageway and the source containing a flowable material being a syringe. Whitehouse et al. disclose that is well known in the art to use a septum to provide a self-sealing seal between a needle and catheter. It would have been obvious to one of ordinary skill in the art at the time the invention was made include a septum in the cavity of the catheter to provide a self-sealing seal between the needle and the catheter so that the inflation medium does not leak out once the needle is removed.

Furthermore, Salama discloses a syringe as an old and well known containing a flowable material. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to select a syringe as the source of flowable material for the Hickey et al. device.

9. Claim 18 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haber and further in view of Andino et al. Haber teaches all of the method steps except placing the implant along two opposite sides of the urethra. Andino et al. teach that it is well known in the art to position periurethral tissue implants along two opposite sides of the urethra to enhance the passive occlusive pressure of the urethral sphincter and thereby achieve continence. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to position the implant of Haber along two opposite sides of the urethra to enhance the effectiveness of the device and increase the passive occlusive pressure of the urethral sphincter.

10. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Haber as applied to claim 13 above, and further in view of Whitehouse et al. Haber teaches all of the limitations of the claims except a septum being contained the port portion. Whitehouse et al. disclose that is well known in the art to use a septum to provide a self-sealing seal between a needle and catheter. It would have been obvious to one of ordinary skill in the art at the time the invention was made to include a septum in the cavity of the catheter to provide a self-sealing seal between the needle and the catheter so that the inflation medium does not leak out once the needle is removed.

Allowable Subject Matter

11. Claim 25 and 38 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments filed 01/14/02 have been fully considered but they are not persuasive.

Applicant argues that Hickey et al. is not a device adapted for implantation within body tissue with an expandable element adjacent a body lumen. The device of Hickey et al. is implanted into the urethra, which constitutes being implanted into tissue. Applicant also argues that Hickey et al. teach away from an apparatus to provide volume to the body tissue for adjustable coaption of a body lumen. Hickey et al. disclose closing the bladder neck, which is coapting of a body lumen.

Applicants' assertion that Examiner is using the Haber 4,846,784 reference is correct. Regarding the argument that Haber fails to show providing a flowable material from a source into the port portion at the rearward end of the elongate implantable device, Applicant is directed to col. 5 lines 41-44. In this portion of the text Haber discloses a flowable material provided from a source (needle) into a port (the proximal end of the cannula) at the rearward end of the device.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosiland S Kearney whose telephone number is 703/3082711. The examiner can normally be reached on Mon.-Fri. 7:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on 703/3080994. The fax phone numbers for the organization where this application or proceeding is assigned are 703/3080758 for regular communications and 703/3080758 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703/3080858.

RK
April 4, 2002